

SUPPLEMENTAL REMARKS

Status of the Claims

Claims 14-17, 19, 20, 22 and 23 are pending in this application. No claims are presently canceled, added or amended. Applicant submits the following remarks and Declaration in support of the allowability of the claims.

Rejections under 35 USC 112, first paragraph

The Examiner rejected claims 14-17 and 19-26 as not enabled for all bacteria having fimbriae. Again, Applicant traverses the rejection and respectfully requests the withdrawal thereof in light of the additional remarks and supporting Declaration under 37 CFR 1.132.

In the Reply filed October 8, 2003, Applicant amended the claims to define the bacteria having fimbriae as enteric bacteria having fimbriae. This subgenus of bacteria having fimbriae is commensurate in scope with the disclosure. This subgenus is defined and supported by the specification. Salmonella bacteria is a representative species within the subgenus of enteric bacteria having fimbriae, which is disclosed and enabled by Example 1.

Applicant also submits that the entire subgenera of enteric bacteria having fimbriae is supported and enabled by the specification. Enteric bacteria are known for attaching to the gut

epithelium of the host by fimbriae. This is the same mechanism used by *Salmonella* when they become pathogenic to the host. *Enterobacteriaceae* are classified as such for this ability to attach to the gut epithelium with fimbriae.

Applicant conducted further experiments with *Citrobacter* and *Klebsiella*, two other bacteria within the subgenus of enteric bacteria having fimbriae. The results of the experiments are reported in the attached Declaration under 37 CFR 1.132 and are shown in Figures 1 and 2 attached to the Declaration. In the Experiments, Dr. Hakalehto studied a strain of *Citrobacter freundii* and a strain of *Klebsiella* species by measuring the immunoreactivities from enrichment cultures using anti-peptide antibodies against enterobacterial type-1 and SEF fimbrial sequences by an EIA assay.

Figures 1 and 2 in the Declaration demonstrate that the immunoreactivities of strains of *Citrobacter* and *Klebsiella* arose in 4 hours, whereas the peak occurred in 5 hours. In view of this data, the earlier onset of fimbrial expression seems to be valid irrespective of the specific species within the subgenus of enteric bacteria having fimbriae.

Again, Applicants also submits that there is no undue experimentation in determining or screening for bacteria having fimbriae. The family of *Enterobacteriaceae* is well known and Applicant has demonstrated with Figures 1 and 2 in the Declaration

(Exhibit A) that other members of the family *Enterobacteriaceae* are detectable with the claimed method.

Pursuant to In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988), the test for enablement is whether one of ordinary skill in the art would have to engage in undue experimentation to practice the invention. In *Wands*, the Federal Circuit found that the claims were enabled even where one of ordinary skill in the art would have to engage in production and screening of numerous monoclonal antibodies to practice the invention.

The present case is similar to the case in *Wands*. In *Wands*, the invention was directed to a method of detecting particular antigens using high affinity monoclonal antibodies of the IgM isotype. The central issue of enablement was whether the screening method (method of determining a high affinity IgM isotype antibody) was unpredictable and unreliable. The specification in *Wands* disclosed a method of producing monoclonal antibodies (by using hybridomas) against the specific antigen. The specification also disclosed working examples. Such is also the case in the present specification. The present specification disclose an ELISA assay for detecting antibodies that are produced in response to fimbrial peptides.

As such, Applicant submits that the claims are enabled for "enteric bacteria having fimbriae" and the rejection regarding the scope of the bacteria should be withdrawn.

Conclusion


Applicants respectfully request that this Supplemental Reply is considered as it further supports the withdrawn of the enablement rejection.

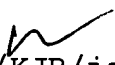
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s): Declaration under 37 C.F.R. § 1.132